UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

MICHAEL PARDI, et al.,

Plaintiffs,

v.

TRICIDA, INC., et al.,

Defendants.

Case No. 21-cv-00076-HSG

ORDER GRANTING MOTION TO CERTIFY CLASS AND APPOINTING CLASS REPRESENTATIVE AND CLASS COUNSEL

Re: Dkt. No. 152

Pending before the Court is Lead Plaintiff's ("Plaintiff") motion to certify a securities class action, appoint Plaintiff as class representative, and appoint Block & Leviton LLP as class counsel. Dkt. No. 152. The Court finds the matter appropriate for disposition without oral argument and the matter is deemed submitted. *See* Civil L.R. 7-1(b). For the reasons below, the Court **GRANTS** the motion.

I. BACKGROUND

A. Factual Background

Tricida is a clinical-stage biopharmaceutical company. Dkt. No. 142 ¶ 40 ("Second Amended Complaint" or "SAC")[1]. Defendant Klaerner was Tricida's Chief Executive Officer and President at the time the SAC was filed. *Id.* ¶ 41. In May 2018, Tricida completed its Phase 3 clinical trial for veverimer, a drug intended to slow the progression of chronic kidney disease ("CKD"). *Id.* ¶¶ 45, 62. Following the trial results, Tricida held its initial public offering ("IPO") on June 28, 2018 and began trading on the Nasdaq Global Select Market. *Id.* ¶¶ 7, 65. In late August 2019, Tricida submitted its New Drug Application ("NDA") for veverimer to the

[1] The Court cites to redacted versions of the pleadings publicly filed on the docket pursuant to its recent sealing order. *See* Dkt. No. 141.

United States Food and Drug Administration ("FDA") under the FDA's Accelerated Approval Program. *Id.* ¶ 71. The FDA accepted Tricida's NDA for review three months later. *Id.*

On July 15, 2020, Tricida disclosed that the FDA had notified it that the agency had "identified deficiencies that preclude discussion of labeling and postmarketing requirements/commitments at this time." *Id.* ¶ 28. Tricida issued another press release on August 24, 2020 stating that it had received a Complete Response Letter from the FDA on August 21, 2020 expressing concerns that Tricida's Phase 3 trial alone might not demonstrate the efficacy of veverimer. *Id.* ¶ 29. Tricida further stated that the FDA sought additional data regarding the magnitude and durability of veverimer's treatment effect and on the applicability of that effect to the U.S. population. *Id.* On October 29, 2020, Tricida announced that the FDA had informed it that the FDA was "unlikely to rely solely on serum bicarbonate data for determination of efficacy" and would "require evidence of veverimer's effect on CKD progression from a nearterm interim analysis of the VALOR-CKD trial for approval under the Accelerated Approval Program." *Id.* ¶ 30. On February 25, 2021, Tricida announced that the FDA had denied the appeal of its NDA denial. *Id.* ¶ 91.

B. Procedural Background

On January 6, 2021, Plaintiff Michael Pardi filed this lawsuit asserting violations of Sections 10(b) and 20(a) of the Securities Exchange Act and Rule 10b-5. Dkt. No. 1 ¶ 1. In April 2021, the Court appointed Jeffrey M. Fiore as Lead Plaintiff and Block & Leviton LLP as Lead Counsel. Dkt. No. 65.

On March 11, 2024, the Court issued an Order Granting in Part and Denying in Part Defendant Klaerner's Motion to Dismiss the Second Amended Complaint, Dkt. No. 145 ("SAC Order"), which incorporated the Court's prior holdings in its July 29, 2022 Order Granting in Part and Denying in Part Klaerner and Tricida, Inc.'s Motion to Dismiss the First Amended Complaint. Dkt. No. 93 ("FAC Order"). The Court found the Second Amended Complaint pleaded actionable claims with respect to Defendant Klaerner's May 7, 2020 statements during an earnings call.[2]

[2] On January 12, 2023, Tricida filed a voluntary bankruptcy petition. Dkt. No. 125. On March 23, 2023, the Court granted Plaintiff's motion to voluntary terminate defendant Tricida. Dkt. No. 132.

On April 30, 2024, Plaintiff moved to certify a class under Rules 23(a) and 23(b)(3) consisting of persons or entities who purchased or otherwise acquired common stock of Tricida from May 8, 2020 to February 25, 2021, with the narrow exclusion of certain parties.

C. Remaining Alleged Misstatements

Plaintiff alleges that he was damaged by Defendant's misrepresentations and omissions because he "purchased Tricida common stock at artificially inflated prices." *Id.* ¶ 34. Two such allegedly false and misleading statements remain in this case. Both revolve around Defendant Klaerner's failure to disclose issues flagged by the FDA at a May 1, 2020 meeting with Tricida. Plaintiff alleges that at that meeting, the FDA in its "Introductory Comments" repeated the "Substantive Review Issues": that (1) the FDA "remain[ed] concerned about the magnitude and durability of the treatment effect," (2) that it was "not clear that the results of TRCA-301/301E were applicable to the U.S. population and practice of medicine," a view informed by the FDA's knowledge that the majority of sites were in Eastern Europe, and (3) that "the treatment effect at Week 52 was driven entirely by a single site in Bulgaria." SAC ¶¶ 75–77.

The first allegedly false and misleading statement was made during a May 7, 2020 earnings call in which Klaerner stated:

> In our late-cycle meeting with [the] FDA, we took the opportunity to address outstanding review issues. We presented our data and rationale as to why we think [veverimer] satisfied the requirements for initial approval under the Accelerated Approval Program, including the magnitude and durability of the treatment effect on the surrogate mark[er] serum bicarbonate demonstrated in the TRCA-301 and TRCA-301E trials.

Id. ¶ 80. The Court held that Plaintiff adequately alleged that Klaerner misled investors by telling them about only one of two "outstanding review issues" discussed at the May 1 meeting: "the magnitude and durability of the treatment effect on the surrogate marker." FAC Order at 22[3]. The Court noted that "by disclosing this key detail, Klaerner was obligated to share the other

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The case thus only proceeds against Defendant Klaerner.

[3] *See also* SAC Order at 8 ("The Court finds that there is no basis to revisit any of its prior rulings, including the statements discussing outstanding review issues with the FDA that the Court previously found to be sufficiently pled.").

significant review issue raised by the FDA—the 'applicability of data from the TRCA-301 and TRCA-301E trials to the U.S. population' discussed with the FDA." *Id.*

The second allegedly false and misleading statement was made during the same call. Klaerner stated:

> In our late-cycle meeting with the FDA, held in May 2020, the FDA indicated it currently does not plan to hold an AdCom to discuss veverimer due in part to the logistical challenges posed by COVID-19.

SAC ¶ 158. The Court held that Plaintiff adequately alleged that Klaerner intentionally or recklessly misrepresented the true reasons for the cancellation of the AdCom meeting because "'[t]he FDA did not cite logistical challenges stemming from COVID-19 as even a contributing factor in canceling the AdCom meeting in its communications with Tricida.'" SAC Order at 17. The Court cited Plaintiff's allegations that the FDA identified "'significant issues" with the trial and their impact on a potential AdCom meeting" that would not "warrant convening an Advisory Committee." *Id.*

II. LEGAL STANDARD

The party seeking class certification bears the burden of demonstrating by a preponderance of the evidence that all four requirements of Rule 23(a) and at least one of the requirements under Rule 23(b) are met. *Wal-Mart Stores, Inc. v. Dukes*, 546 U.S. 338, 350-51 (2011).

Rule 23(a) sets four threshold requirements for class certification: (1) the class must be "so numerous that joinder of all members is impractical" ("numerosity"); (2) "there must be questions of law or fact common to the class" ("commonality"); (3) "the claims . . . of the representative parties" must be "typical of the claims . . . of the class" ("typicality"); and (4) the representative parties must "fairly and adequately protect the interests of the class" ("adequacy"). Fed. R. Civ. P. 23(a). Once a proposed class meets these four requirements, the court then must determine whether the action can be maintained under one of the three subsections of Rule 23(b).

Plaintiff seeks certification under Rule 23(b)(3), which requires the Court to find "that the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and

efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). Where "one or more of the central issues in the action are common to the class and can be said to predominate, the action may be considered proper under Rule 23(b)(3) even though other important matters will have to be tried separately, such as damages or some affirmative defenses peculiar to some individual class members." *Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. 442, 453 (2016) (citing C. Wright, A. Miller, & M. Kane, Federal Practice and Procedure § 1778, pp. 123–124 (3d ed. 2005)).

"Rule 23 grants courts no license to engage in free-ranging merits inquiries at the certification stage." *Amgen Inc. v. Conn. Ret. Plans & Tr. Funds*, 568 U.S. 455, 466 (2013). "Merits questions may be considered to the extent – but only to the extent – that they are relevant to determining whether the Rule 23 prerequisites for class certification are satisfied." *Id.* Courts "must take the substantive allegations of the complaint as true" but "need not accept conclusory or generic allegations regarding the suitability of the litigation for resolution through class action." *Keilholtz v. Lennox Hearth Prods. Inc.*, 268 F.R.D. 330, 335 (N.D. Cal. 2010) (citation omitted).

Plaintiff bears the burden of demonstrating that common questions will predominate over individual ones under Rule 23(b)(3) by a preponderance of the evidence. *Olean Wholesale Grocery Coop., Inc. v. Bumble Bee Foods LLC*, 31 F.4th 651, 665 (9th Cir. 2022). The Court considers whether Plaintiff has demonstrated that "the same evidence will suffice for each member to make a prima facie showing or the issue is susceptible to generalized, class-wide proof," or if "members of a proposed class will need to present evidence that varies from member to member." *Tyson Foods*, 577 U.S. at 453.

III. DISCUSSION

A. Rule 23(a)

i. Typicality

Defendant challenges only typicality under Rule 23(a). Rule 23(a)(3) requires that "the claims or defenses of the representative parties are typical of the claims or defenses of the class." Fed. R. Civ. P. 23(a)(3). The "test of typicality is whether other members have the same or similar injury, whether the action is based on conduct which is not unique to the named plaintiffs, and whether other class members have been injured by the same course of conduct." *Hanon v.*

Dataproducts Corp., 976 F.2d 497, 508 (9th Cir. 1992). A plaintiff's claims are considered typical if they are "reasonably co-extensive with those of absent class members; they need not be substantially identical." *Castillo v. Bank of Am., NA*, 980 F.3d 723, 730 (9th Cir. 2020). A plaintiff may not be typical if she is "subject to unique defenses which threaten to become the focus of the litigation." *Hanon*, 976 F.2d at 508. However, "[d]iffering factual scenarios resulting in a claim of the same nature as other class members does not defeat typicality." *Ellis v. Costco Wholesale Corp.*, 657 F.3d 970, 985 n.9 (9th Cir. 2011) (citing *Hanon*, 976 F.2d at 508).

Defendant first contends that the Class Period ended on July 16, 2020, the day after Defendant's purportedly full corrective disclosure on July 15, 2020. Defendant argues that Plaintiff is subject to unique defenses relating to damages and reliance because he made his stock purchase on July 16, 2020, after the stock had already absorbed approximately 90% of that disclosure's alleged impact. As discussed below in the predominance analysis, the Court rejects Defendant's contention that the relevant price inflation dissipated before Plaintiff's purchase.

Defendant next argues that Plaintiff is atypical because he has testified that he did not know about the May 7, 2020 challenged statements and did not know or believe that the market price incorporated publicly available information. However, Plaintiff alleges that he purchased Tricida common stock at prices that were artificially inflated due to Defendant's material misrepresentations and omissions, and his deposition testimony reflects the same. *See* Dkt. 163 ("Wechkin Decl."), Ex. 16 at 118:11-15 (Q: "Did you believe that the price at which you purchased the stock incorporated all of the news about Tricida that was publicly available?" A: "Yeah.") This showing is sufficient for typicality. *See In re FibroGen Sec. Litig.*, 2024 WL 1064665, at *4 (N.D. Cal. Mar. 11, 2024) ("The underlying merits of the case, while admittedly relevant at the class certification stage, should not overly cloud the Court's certification analysis—the only question presently before the Court is whether the requirements of Rule 23 are met"); *Hanon*, 976 F.2d at 509 ("We emphasize that the defense of non-reliance is not a basis for denial

of class certification.").[4]

The Court now briefly addresses the uncontested Rule 23(a) factors.

ii. Numerosity

"As a general rule, classes numbering greater than forty individuals satisfy the numerosity requirement." *Barnes v. AT & T Pension Benefit Plan-Nonbargained Program*, 270 F.R.D. 488, 493 n.2 (N.D. Cal. 2010). "Where the exact size of the proposed class is unknown, but general knowledge and common sense indicate it is large, the numerosity requirement is satisfied." *In re HiEnergy Techs., Inc. Sec. Litig.*, 2006 WL 2780058, at *3 (C.D. Cal. Sept. 26, 2006). During the Class Period, shares of Tricida stock traded at an average weekly volume of 4.55 million shares, and 198 institutions, whose holdings accounted for the "vast majority of the public float," held shares of Tricida. Dkt. 153-1 ¶¶ 34, 78 (Coffman Report). Numerosity is satisfied given the number of investors that purchased Tricida stock during the Class Period.

iii. Common Questions of Law and Fact

"So long as there is 'even a single common question,' a would be class can satisfy the commonality requirement of Rule 23(a)(2)." *Parsons v. Ryan*, 754 F.3d 657, 675 (9th Cir. 2014). Common questions in this case include: (i) whether Defendant made materially false and misleading statements and omitted material facts during the Class Period; (ii) whether Defendant acted with scienter; (iii) whether Defendant's alleged misrepresentations and omissions were material; and (iv) whether Defendant alleged misconduct caused investors to suffer damages. As a result, the commonality requirement is met.

iv. Adequacy

The adequacy requirement has two components: "(1) whether there are conflicts within the class; and (2) whether plaintiffs and counsel will vigorously fulfill their duties to the class." *Amey v. Cinemark USA Inc.*, 2018 WL 3956326, at *6 (N.D. Cal. Aug. 17, 2018) (citing *Ellis v. Costco*

[4] Nor does Plaintiff's partial reliance on Tricida's July 15, 2020 disclosure—which is not an actionable misstatement in this case—subject him to unique defenses or render him an atypical class member.

Wholesale Corp., 657 F.3d 970, 985 (9th Cir. 2011)). Plaintiff and Lead Counsel contend that they have no conflicts of interest with other class members and that they have worked diligently to protect the Class's interests. *See* Dkt. No 152-2 (Fiore Decl). Defendant does not dispute either contention. Accordingly, the Court holds that Plaintiff has satisfied the requirements under Rule 23(a).

B. Rule 23(b)

v. Superiority

Defendant does not challenge whether a class action is superior to individual actions under Rule 23(b)(3), but the Court briefly addresses the question here. Courts examine four factors to determine superiority: (1) the class members' interests in individually controlling the prosecution or defense of separate actions; (2) the extent and nature of any litigation concerning the controversy already begun by or against class members; (3) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and (4) the likely difficulties in managing a class action. Fed. R. Civ. P. 23(b)(3)(A)-(D). As for the first factor, Plaintiff contends that the proposed Class is dispersed around the country and the cost of litigating on an individual basis is much higher than any likely individual recovery. As for the second factor, Plaintiff is unaware of any other Section 10(b) actions against Defendant related to the fraud alleged here. As for the third factor, concentration of this litigation in this forum promotes efficiency and avoids inconsistent adjudication. As for the final factor, Plaintiff does not anticipate any management difficulties in maintaining this case as a class action. Accordingly, superiority is satisfied.

vi. Predominance

a. The *Basic* Presumption

Here, whether the predominance requirement of Rule 23(b) is satisfied hinges on whether reliance can be resolved on a class-wide basis. Plaintiff seeks Rule 23(b)(3) class certification of claims alleged under Sections 10(b) and Rule 20(a), each of which requires a showing of reliance on a materially untrue or misleading statement. To prove reliance on a class-wide basis, Plaintiff invokes the fraud-on-the-market presumption created in *Basic, Inc. v. Levinson*, 485 U.S. 224

(1988). The "fraud on the market" presumption arose as a practical response to the difficulties of proving direct reliance in the context of modern securities markets, where impersonal trading rather than a face-to-face transaction is the norm. *SEB Inv. Mgmt. AB v. Symantec Corp.*, 335 F.R.D. 276, 283 (N.D. Cal. 2020). The presumption is based on the well-founded principle that "a public, material misrepresentation will distort the price of stock traded in an efficient market, and that anyone who purchases the stock at the market price may be considered to have done so in reliance on the misrepresentation." *Halliburton Co. v. Erica P. John Fund, Inc.*, 573 U.S. 258, 283, (2014) ("*Halliburton II*"). To invoke the *Basic* presumption, Plaintiff must show: "(1) the alleged misrepresentations were publicly known, (2) that they were material, (3) that the stock traded in an efficient market, and (4) that the plaintiff traded the stock between the time when the misrepresentations were made and when the truth was revealed." *Id.* at 268. When the presumption applies, investors do not need to demonstrate individual reliance. *Basic*, 485 U.S. at 241–47. A defendant can "rebut the [fraud-on-the-market] presumption of reliance" by demonstrating that "news of the [truth] credibly entered the market and dissipated the effects of [prior] misstatements." *Id.* at 248–249. *Basic* emphasized, however, that "[p]roof of that sort is a matter for trial (and presumably also for a summary-judgment motion under Federal Rule of Civil Procedure 56)." *Id.* at 249 n.29.

b. *Amgen* and *Halliburton II* Raise Questions as to the Application of *Basic*

Two Supreme Court decisions following *Basic* discuss the boundaries of the doctrine. In *Amgen Inc v. Connecticut Ret. Plans & Tr. Funds*, the Supreme Court held that a plaintiff did not have to prove materiality at class certification because materiality was a merits issue rather than a predominance issue. 568 U.S. 455, 459 (2013). *Amgen* also reasserted *Basic*'s holding that it was not appropriate to consider evidence relating to truth on the market at class certification. *Id.* at 482. In *Halliburton II*¸ the Supreme Court narrowed the scope of *Basic*'s fraud on the market presumption by allowing defendants to rebut that presumption at class certification based on evidence of a *lack* of price impact. *Halliburton II* noted that "[d]efendants must be afforded an opportunity before class certification to defeat the [*Basic*] presumption through evidence that an

alleged misrepresentation did not actually affect the market price of the stock." *Id.* at 284. The Supreme Court further commented that "[u]nder *Basic*'s fraud-on-the-market theory, market efficiency and the other prerequisites for invoking the presumption constitute an indirect way of showing price impact . . . [, b]ut an indirect proxy should not preclude direct evidence when such evidence is available." *Id.* at 281. "While *Basic* allows plaintiffs to establish that precondition indirectly, it does not require courts to ignore a defendant's direct, more salient evidence showing that the alleged misrepresentation did not actually affect the stock's market price and, consequently, that the *Basic* presumption does not apply." *Id.* at 282.

In key ways, proving a lack of price impact under *Halliburton II* implicates arguments and evidence required to prove merits issues, including materiality. This puts courts in the potentially challenging position of assessing predominance without "'thinking about a pink elephant,' i.e., without paying attention to the obvious implications for the merits." *In re Allstate Corp. Sec. Litig.*, 966 F.3d 595, 602 (7th Cir. 2020). The tension between *Amgen* and *Halliburton II* was particularly salient in cases involving the truth on the market defense, where a defendant argues that a misrepresentation can no longer maintain a price impact because the market was already aware of the truth regarding the misrepresentations. "[B]ecause the market's knowledge of the truth has no bearing on whether the alleged misrepresentation was publicly known," courts have interpreted the truth on the market defense as "merely an argument that the alleged misrepresentation was immaterial in light of other information on the market." *Aranaz v. Catalyst Pharm. Partners Inc.*, 302 F.R.D. 657, 671 (S.D. Fla. 2014); *see also Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 167 (2d Cir. 2000) ("[A] misrepresentation is immaterial if the information is already known to the market because the misrepresentation cannot then defraud the market."); *Provenz v. Miller*, 102 F.3d 1478, 1492 (9th Cir. 1996) ("In a 'fraud on the market' case an omission is materially misleading only if the information has not already entered the market.") (internal quotations omitted); *Virginia Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1097 (1991) (holding that true statements may discredit a false statement such that the risk of deception decreases to the point that the misstatement is immaterial).

Following *Amgen* and *Halliburton II*, courts were understandably reluctant to consider truth on the market defenses at class certification. On remand, the *Halliburton II* district court noted:

> *Amgen* and *Halliburton I* strongly suggest that the issue of whether disclosures are corrective is not a proper inquiry at the certification stage. *Basic* presupposes that a *misrepresentation* is reflected in the market price at the time of the transaction. Thus, at this stage of the proceedings, the Court concludes that the asserted misrepresentations were, in fact, misrepresentations, and assumes that the asserted corrective disclosures were corrective of the alleged misrepresentations. To hold otherwise would require the Court to pass judgment on the merits of the allegations after the dismissal stage and before summary judgment—in effect, giving a third bite at the apple to Halliburton. While it may be true that a finding that a particular disclosure was not corrective as a matter of law would "sever the link between the alleged misrepresentation and ... the price received (or paid) by the plaintiff ....," the Court is unable to unravel such a finding from the materiality inquiry . . . In other words, if Halliburton were to successfully persuade the Court at summary judgment that a particular disclosure was not corrective, it would end this controversy altogether.

Erica P. John Fund, Inc. v. Halliburton Co., 309 F.R.D. 251, 261–62 (N.D. Tex. 2015) (internal citations removed); *see also Aranaz*, 302 F.R.D. at 671 ("[f]or purposes of determining at this early stage in litigation whether the alleged misrepresentation had any impact on the price of Catalyst stock, the Court must disregard evidence that the truth was known to the public."). Courts were also wary of shortening class periods based on truth on the market defenses, as determining exactly when the truth was revealed to the market implicates a factual finding as to the materiality of the statement. *See Mulderrig v. Amyris, Inc.*, 340 F.R.D. 575, 583 (N.D. Cal. 2021) (citing *In re Snap Inc. Sec. Litig.*, 334 F.R.D. 209, 225 (C.D. Cal. 2019) ("any inquiry as to precisely when the truth was fully disclosed to the market is best reserved for resolution on the merits, and should not result in the Court's narrowing of the class period at class certification unless the defendant 'unequivocally' disclosed the alleged prior representation."); *Karinski v. Stamps.com, Inc.*, 2020 WL 6572660, at *7 (C.D. Cal. Nov. 9, 2020) (same); *Monroe Cty. Employees' Ret. Sys. v. Southern Co.*, 332 F.R.D. 370, 395 (N.D. Ga. 2019) (collecting cases).[5]

[5] *But see Carpenters Pension Tr. Fund of St. Louis v. Barclays PLC*, 310 F.R.D. 69, 97 (S.D.N.Y. 2015) (internal citations and quotations removed) ("Courts are required to cut off the class period on the date of a statement or event that cures the market. In other words, a class period ends when

c. The Supreme Court's Discussion of the *Basic* Analysis in *Goldman*

The Supreme Court further addressed the *Basic* doctrine in *Goldman Sachs Group v. Arkansas Teacher Retirement System*, 141 S. Ct. 1951 (2021) ("*Goldman*"). *Goldman* held that a defendant can rebut the *Basic* presumption by demonstrating, by a preponderance of the evidence, that the misrepresentations did not actually affect, or impact, the market price of the stock. *Id.* at 1963. "*All* probative evidence"—"qualitative as well as quantitative"— is relevant "to assessing price impact at class certification." *Id.* at 1960 (emphasis in original). A court should also apply "a good dose of common sense" in this analysis. *Id.* But "[t]he defendant must 'in fact' 'sever the link' between a misrepresentation and the price paid by the plaintiff—and a defendant's mere production of some evidence relevant to price impact would rarely accomplish that feat." *Id.* at 1962. The Court also explained that "[t]he district court must use the evidence to decide the price impact issue while resisting the temptation to draw what may be obvious inferences for the closely related issues that must be left for the merits." *Id.* at 1961 n.2 (internal citation and quotation removed).

After setting out these guidelines, *Goldman* specifically addressed price impact in cases where a misrepresentation allegedly maintained inflation that is already built into the stock price. Courts measure this inflationary effect by looking to changes in the stock price after the truth is finally disclosed: if the stock price drops, this "back-end" price drop serves as indirect evidence of "front-end" inflation. *Goldman* explained that the "inference [ ] that the back-end price drop equals front-end inflation [ ] starts to break down" when the earlier misrepresentation is generic and the later corrective disclosure is specific. *Id.* at 1961. Under those circumstances, the Court noted that "it is less likely that the specific disclosure actually corrected the generic misrepresentation." *Id.* The generic nature of a misrepresentation can thus serve as "important evidence of price impact that courts should consider at class certification, including in inflation-maintenance cases." *Id.* at 1960.

In short, *Goldman* held that to determine the absence of price impact a court can analyze the corrective nature of a disclosure and make factual findings as to a truth on the market defense,

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the truth has been disseminated to the market.")

even if that analysis overlaps with merits issues like materiality. Though *Goldman* gives guidance regarding a court's general task at class certification, the decision "requires careful trekking"—to say the least—as it relates to merits-only issues. *Arkansas Tchr. Ret. Sys. v. Goldman Sachs Grp., Inc.*, 77 F.4th 74, 81 (2d Cir. 2023). Relevant here, *Goldman* allows a court to make a finding of fact based on "all probative evidence" that the truth was disclosed to the market. Any such factual finding necessarily implicates conclusions of fact relating to materiality, even if the court avoids thinking of the "pink elephant" of materiality in its analysis. At the merits stage, however, parties will very likely point to the court's findings of fact relevant to materiality, raising questions as to whether the court has conclusively determined these factual issues in deciding class certification. Arguably, resolving predominance could require essentially a mini-trial with inescapable implications for the merits, in advance of a full trial regarding the actual merits. For now, following the letter of *Goldman*, this Court will not credit arguments from the parties at the merits stage assuming "what may be obvious inferences" from its class certification decision. *Goldman* at 1961 n.2 (internal citation and quotation removed). Any findings of fact in this decision are cabined to the class certification analysis.

d. Applying *Goldman's* Mismatch Framework

The Court now analyzes the mismatch framework under *Goldman*. A recent decision in this district laid out the following helpful test under *Goldman*: "A finding of 'back-end' price impact requires proof that the information disclosed . . . was (i) corrective of one or more prior false statements or omissions, (ii) new (unknown to the market prior to [the purported corrective disclosure date]), and (iii) 'value-relevant' (*i.e.*, caused at least some of the stock price decline)." *In re FibroGen Sec. Litig.*, 2024 WL 1064665, at *12.

"It is [d]efendants' burden to show the *absence* of price impact – not merely to challenge Plaintiff on the persuasiveness of its own price impact claim – once *Basic*'s presumption of reliance attaches." *In re Allergan PLC Sec. Litig.*, 2021 WL 4077942, at *10 (S.D.N.Y. Sept. 8, 2021) (internal citation and quotation removed). Avoiding a "mismatch" "requires a closer fit (even if not precise) between the front- and back-end statements than courts have required when analyzing the loss causation element of securities fraud." *In re Kirkland Lake Gold Ltd. Sec.*

Litig., 2024 WL 1342800, at *6 (S.D.N.Y. Mar. 29, 2024) (citing *Arkansas Tchr. Ret. Sys.*, 77 F.4th at 99 n.11). A mismatch in subject matter also severs the link between the challenged statement and the purported corrective disclosure. *In re Kirkland Lake Gold Ltd. Sec. Litig.*, 2024 WL 1342800, at *11 (price impact disproved where "there is a substantive mismatch" between the challenged statement and the purported corrective disclosure). However, a corrective disclosure "need not precisely mirror the earlier misrepresentation." *In re BofI Holding, Inc. Sec. Litig.*, 977 F.3d 781, 790 (9th Cir. 2020) (quotation omitted). "It is enough if the disclosure reveals new facts that, taken as true, render some aspect of the defendant's prior statements false or misleading." *Id.* Further, "the true facts concealed by the defendant's misstatements may be revealed over time through a series of partial disclosures." *Id.*

Defendants may also show that a challenged statement ceased to impact stock price at a particular point in a putative class period. *See Ferris v. Wynn Resorts Ltd.*, 2023 WL 2337364, at *11 (D. Nev. Mar. 1, 2023) (under the "mismatch" analysis, class "may not proceed" as to one purported corrective disclosure). [6]

e. Analysis

The Court briefly addresses the undisputed *Basic* factors. First, Defendant does not

[6] Plaintiff cites *Homyk v. Chemocentryx*, 21-cv-03343-JST, 2024 WL 1141699, at *4 (N.D. Cal. Mar. 6, 2024) for the proposition that the "inquiry is whether defendant has proven a complete lack of price impact during the Class Period, not whether the stock price decline following individual corrective disclosures was caused by the alleged misrepresentations[.]" This is an uncontroversial assertion: to rebut the *Basic* presumption, a defendant must sever the link between a misrepresentation and the price paid by Plaintiff. If a defendant fails to rebut the *Basic* presumption and a plaintiff meets all the other elements for class certification, the court certifies a class of some duration. But contrary to Plaintiff's apparent implication, *Homyk* did not adopt the pre-*Goldman* strain of case law that courts should not "shorten class periods by dismissing subsequent corrective disclosures where some but not all of the stock price declines following the alleged corrective disclosures were statistically significant." *Monroe Cty. Employees' Ret. Sys*, 332 F.R.D. at 395; *see also Bos. Ret. Sys. v. Alexion Pharms., Inc.*, 2023 WL 2932485, at *12 (D. Conn. Apr. 13, 2023). The *Homyk* defendants argued that because a full corrective disclosure occurred on May 4, 2021, the May 6, 2021 disclosure could not have a back-end price impact. *See Homyk*, 21-cv-03343-JST, Dkt. No. 87 at 36–37. The court noted that both disclosures were corrective, a point which mooted the argument to curtail the class period. *See Homyk* at *5 ("On the back-end, Defendants failed to sever the link between the corrective disclosures on May 4, 2021 and May 6, 2021 and the statistically significant price impacts on May 5, 2021 and May 7, 2021.")

dispute that the misrepresentations at issue were publicly known. Second, the materiality of the statements need not be proven at the class certification stage. Third, Defendant does not dispute that Tricida common stock traded in an efficient market during the class period. Fourth, Defendant does not dispute that Plaintiff traded the stock between the time when the misrepresentations were made and when the truth was revealed. Because Plaintiff's entitlement to the presumption is undisputed, the burden shifts to Defendant to rebut the presumption, which Defendant seeks to do for a portion of the class period.

Plaintiff does not argue that Defendant's alleged misstatements caused any front-end price impact. Instead, Plaintiff argues that the alleged misstatements artificially inflated the stock price through February 25, 2021, when Defendant revealed the full account of the FDA's concerns raised at the May 1, 2020 meeting. Defendant, in turn, contends the class period must end on July 16, 2020, the day after the first purported fully corrective disclosure. He further contends that purported corrective disclosures after August 6, 2020 neither corrected the challenged statements nor introduced new information about the May 1, 2020 meeting into the market. To resolve the end date of the Class Period, the Court must first address the scope of the allegedly omitted information as to either remaining statement.

As for the first statement, this Court held that Plaintiff has adequately alleged that Defendant misled investors by telling them about only one of two "outstanding review issues" discussed at the May 1 meeting: "the magnitude and durability of the treatment effect on the surrogate marker." FAC Order at 22. By disclosing this "key detail," Defendant was obligated to share the other significant review issue raised by the FDA—the 'applicability of data from the TRCA-301 and TRCA-301E trials to the U.S. population' discussed with the FDA." *Id.* The Court further noted that Plaintiff adequately alleged that "Defendants knew the nature of the FDA's concerns with their clinical data, and that those concerns affected veverimer's chances for FDA approval." *Id*. at 23. The Court explained that Plaintiff's "allegations support a plausible inference that Klaerner informed investors of the good news – the discussion of 'review issues' with the FDA – without including the bad news from the same meeting – the discussion of the FDA's concerns with the 'applicability' of Defendants' clinical data." *Id.*

Plaintiff contends that specific details about the applicability of Tricida's clinical data constitute omitted facts per the Court's orders. As noted, these details include that the FDA in its "Introductory Comments" repeated the "Substantive Review Issues" that (1) the FDA "remain[ed] concerned about the magnitude and durability of the treatment effect," (2) that it was "not clear that the results of TRCA-301/301E were applicable to the U.S. population and practice of medicine," a view informed by the FDA's knowledge that the majority of sites were in Eastern Europe, and (3) that "the treatment effect at Week 52 was driven entirely by a single site in Bulgaria." SAC ¶¶ 75–77. In response, Defendant cites the precise language in the FAC order as to the first representation, which noted that the omitted fact was "other significant review issue raised by the FDA— the 'applicability of data from the TRCA-301 and TRCA-301E trials to the U.S. population' discussed with the FDA." The Court finds that the specific concerns contained in the third category Plaintiff identified qualify as details of "discussion of the FDA's concerns with the 'applicability' of Defendants' trial data," even if the Court did not specifically detail those facts in the Orders, because Plaintiff alleged that the FDA raised these issues in the May 1, 2020 meeting.

As for the second statement, the Court held that Plaintiff has adequately alleged that Klaerner misled investors because "'[t]he FDA did not cite logistical challenges stemming from COVID-19 as even a contributing factor in canceling the AdCom meeting in its communications with Tricida.'" SAC Order at 17. The Court noted that it is "obviously relevant whether the meeting was canceled for 'logistical reasons' or substantive ones, and it was also relevant what the full substantive reasons were once Klaerner chose to highlight some of them." *Id.* at 24; *see also id.* ("It is plausible that a seasoned pharmaceutical executive like Klaerner would be aware that the FDA's reasons for canceling a critical meeting would be highly significant to investors.") Plaintiff argues that the details about the substantive concerns constitute actionable omissions per the Court's Orders. Defendant argues that the Court generally rejected Plaintiff's attempt to shoehorn all the various concerns the FDA expressed during the years-long review process into his theory of falsity. *See* SAC Order at 10–15. This discussion, however, did not apply to the second alleged misstatement relating to the AdCom cancellation. As discussed here, Defendant's second

alleged misstatement invoked a duty to disclose the substantive concerns raised by the FDA at the May 1, 2020 meeting in particular.

A fully corrective disclosure must therefore, in conjunction with previously available information, have informed the market of the three substantive concerns raised by the FDA as listed above. The Court traces the disclosures below, finding that the February 25, 2021 disclosure was the first to inform the market of the allegedly omitted facts.

1. July 15, 2020 Disclosure

On July 15, 2020, Tricida disclosed that it received a letter from the FDA in which it "identified deficiencies that preclude discussion of labeling and postmarketing requirements/commitments at this time." In the same disclosure, however, Tricida noted that the "notification does not specify the deficiencies identified by the FDA." Plaintiff alleges that Tricida already knew of those specific, substantive deficiencies from its May 1, 2020 meeting and continued to conceal them from investors. SAC ¶ 28. Accordingly, the July 15, 2020 announcement cannot constitute a full corrective disclosure.

2. August 6, 2020 Disclosure

Defendant next contends that all relevant information entered the market on August 6, 2020, in its Form 10-Q:

> In our late cycle meeting with the FDA, held in May 2020, we addressed two substantive review issues that the FDA had raised in advance of the meeting, namely concerns related to the magnitude and durability of the treatment effect on the surrogate marker of serum bicarbonate demonstrated in the TRCA-301 and TRCA-301E trials and the applicability of data from the TRCA-301 and TRCA- 301E trials to the U.S. population.
>
> While we plan to work with the FDA to resolve the deficiencies referenced in the July 14, 2020 letter, we require additional information from the FDA before we can evaluate whether and how we will be able to address those deficiencies. We believe we are likely to receive that clarification in the form of a Complete Response Letter, or CRL[2]. Consequently, at this time we do not believe we will receive approval to market veverimer in the United States by our PDUFA goal date of August 22, 2020, if at all.

Dkt. No. 78-6 at 21–22 (2Q 2020 Form 10-Q). This disclosure effectively revealed the first category identified by Plaintiff: concerns related to the magnitude and durability of the treatment

effect on the surrogate marker of serum bicarbonate demonstrated in the TRCA-301 and TRCA-301E trials. Defendant argues that by disclosing that the FDA discussed concerns with "applicability" to "the U.S. population" of data from clinical trials whose population was not restricted to the U.S., Tricida effectively revealed that the FDA was concerned with geographical applicability, which he argues encompasses the second category identified by Plaintiff. Even so, this disclosure does not encompass the substantive point informing the concerns behind geographic applicability: the fact that the majority of sites were in Eastern Europe. Nor does it reveal the third specific substantive concern raised at the May 1, 2020 meeting. As such, it is not fully corrective of either alleged misstatement.

3. August 24, 2020 Disclosure

Before market open on August 24, 2020, Tricida issued a press release announcing that it had received a Complete Response Letter ("CRL") from the FDA. The press release stated:

> According to the CRL, the FDA is seeking additional data beyond the TRCA-301 and TRCA-301E trials regarding the magnitude and durability of the treatment effect of veverimer on the surrogate marker of serum bicarbonate and the applicability of the treatment effect to the U.S. population. [The] FDA also expressed concern as to whether the demonstrated effect size would be reasonably likely to predict clinical benefit.

SAC ¶ 177. The Court does not find this disclosure to be corrective as it does not encompass the specific substantive concerns raised at the May 1, 2020 meeting. Even if these new developments might involve the implications of allegedly omitted facts, the disclosure reveals only new regulatory developments and FDA opinions.

4. October 29, 2020 Disclosure

Before market open on October 29, 2020, Tricida issued a press release announcing that on October 20, 2020, it held a "Type A meeting" with the FDA's Division of Cardiology and Nephrology. SAC ¶ 180. Tricida announced that it now believed that the FDA was "unlikely to rely solely on serum bicarbonate data for determination of efficacy" and that it believed the FDA would "require evidence of veverimer's effect on CKD progression from a near-term interim analysis of the VALOR-CKD trial for approval under the Accelerated Approval Program." *Id.* According to the announcement, it did not believe it could provide a near-term interim analysis

"without compromising the integrity of the ongoing [VALOR-CKD] trial." *Id.*

The Court does not find this disclosure corrective, as it does not involve a revelation of allegedly omitted facts. Instead, this disclosure details new regulatory developments and FDA opinions.

5. February 25, 2021 Disclosure

On February 25, 2021, after market close, Tricida issued a press release announcing it had received an Appeal Denied Letter ("ADL") from the Office of New Drugs ("OND") of the FDA in response to its formal dispute resolution request (FDRR) submission. SAC ¶ 185. The press release described the FDA's apparent concerns, stating that:

> In the ADL, the OND acknowledged that the TRCA-301/TRCA-301E trial met its serum bicarbonate endpoints with statistical significance but concluded that the extent of serum bicarbonate increase observed in the TRCA-301/TRCA-301E trial is not reasonably likely to provide a discernible reduction in CKD progression . . . The OND also provided feedback on other concerns that are particularly relevant in an NDA supported by a single registrational trial. The OND noted concerns around the trial results being strongly influenced by a single site, and the majority of sites for the TRCA-301/TRCA-301E trial being in Eastern Europe, where differences in patient management, including concomitant medications and diet, might affect the treatment response to veverimer and raise a concern of the applicability to a U.S. patient population.

Dkt No. 78-16 at 1. Plaintiff contends that this announcement publicly disclosed for the first time that the trial's results were "strongly influenced by a single site," and "the majority of sites for the TRCA-301/TRCA-301E trial" were in Eastern Europe, "where differences in patient management … might affect the treatment response to veverimer." *See* Dkt. No. 175-2 (Coffman Rebuttal Report) ¶¶ 34–36. Plaintiff argues that this disclosure revealed the full scope of the alleged omitted facts for the first time, correcting Defendant's previous misstatements.

Defendant cites previously disclosed facts to argue that this information was revealed to the market. Specifically, he contends that the market previously knew that the veverimer NDA was based on a single registrational trial (Wechkin Decl., Ex. 7 at 35); that Tricida cautioned investors that the FDA generally requires more than one trial (*id.*, Ex. 8 at 28–29); and that the market had known since August 6, 2020 that the FDA raised concerns about geographical

applicability in connection with the May 1 meeting. However, these facts did not allow the reasonable investor to conclude that the FDA had specifically raised substantive concerns that the trial results were strongly influenced by a single site in Bulgaria and that the majority of sites for the TRCA-301/TRCA-301E trial were located in Eastern Europe, where differences in patient management could raise a concern of the applicability to a U.S. patient population. As such, the Court finds that this information was both corrective and new. This finding is supported by analyst reaction,[7] which specifically noted the newly disclosed facts:

> **J.P. Morgan:** "the ADL noted other concerns in the CRL including the reliability of the data given the disproportionate impact of data from a single high-enrolling trial site and the applicability of the results to US patients given the majority of patients enrolled in TRCA-301/TRCA-301E were from Eastern Europe . . . That said, we still see the possibility of FDA concern about the data's applicability to US patients as a potential review issue as the majority of early enrollment (and therefore likely the earlier events) for VALOR-CKD came from outside of the US or US-like regions.
>
> **Cowen:** While the FDRR had focused on whether the serum bicarbonate changes observed in TRCA-301/TRCA-301E were likely to slow CKD progression, the OND's response highlighted other deficiencies […] In particular, the OND's response highlighted a number of deficiencies the FDA perceives in veverimer's Ph. III TRCA-301/TRCA-301E trial. Issues include the reliability of the data (impact of a single high-enrolling site) and the applicability of the trial to U.S. patients (most subjects were enrolled in regions not considered "U.S.-like"). In the view of the OND, the extent of serum bicarb changes observed in '301/'301E is not likely to provide a discernible reduction in CKD progression.

Coffman Rebuttal Report ¶ 41. The Court also finds that the disclosure was value relevant: Tricida's stock price fell 30.57% in response to these revelations, from a closing price of $7.36 per share on February 25, 2021, to $5.11 per share at market close on February 26, 2021, amounting to a $93 million loss of market capitalization. Both parties' experts find this drop to be statistically significant. *See* Coffman Rebuttal Report ¶ 40; Wechkin Decl., Ex. 3 at 9 (Zurek Report).

The Court rejects Defendant's argument that the February 25, 2021 disclosure is consistent

[7] Generally, the Court does not find a dissection of subjective analyst reporting to be dispositive—or even particularly compelling—evidence regarding price impact. But *Goldman* commands the Court to consider all evidence, so it does so.

with the materialization of previously disclosed regulatory risks. Those disclosures included the possibility that veverimer would not be approved on a timely basis (if at all) through the Accelerated Approval Program, that the FDA might require additional clinical trials to support approval, and that the FDA would not accept its foreign clinical data. Zurek Report ¶ 66. Disclosures that warn that "risks could occur when, in fact, those risks had already materialized" are materially misleading. *In re Facebook Inc. Sec. Litig.*, 87 F.4th 934, 948–49 (9th Cir. 2023) (citing *In re Alphabet Sec. Litig.*, 1 F.4th 687, 702–05 (9th Cir. 2021)). By May 7, 2020, the FDA informed Tricida of the substantive concerns about the issues that Tricida had only warned investors "might" arise. As such, the purported risk disclosures do not shield Defendant from the alleged misrepresentations and cannot negate the apparent back-end price impact of the February 25, 2021 disclosure.

* * *

Defendant fails to sever the price impact from the full corrective disclosure on February 25, 2021. The Court finds that Defendant has failed to rebut the *Basic* presumption. Because the *Basic* presumption applies, Plaintiff will not need to show that individual class members were aware of, and relied upon, Defendant's alleged misrepresentations. Instead, class members may be presumed to have relied on the integrity of Tricida's stock price.[8] The Court therefore finds that Plaintiff has satisfied the predominance requirement.

IV. CONCLUSION

The Court **GRANTS** Plaintiff's motion for class certification and certifies a class of investors defined as:

> All persons or entities who purchased or otherwise acquired common stock of Tricida, Inc. during the period from May 8, 2020 to February 25, 2021, inclusive (the "Class Period"). Excluded from the Class are defendant and Tricida, Inc. and their families, the officers, directors, and affiliates of Defendant and Tricida, Inc., at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns, and any entity in which Defendant or Tricida, Inc. have or had a controlling interest.

[8] Because the *Basic* presumption applies, this Order need not reach Plaintiff's alternative argument that the *Affiliated Ute* presumption of reliance also applies.

The Court further **ORDERS** that Lead Plaintiff Jeffrey M. Fiore is appointed as Class Representative and **ORDERS** that Lead Counsel Block & Leviton LLP shall serve as Class Counsel.

The Court further SETS a telephonic case management conference on October 22, 2024, at 2:00 p.m. The hearing will be held by Public Zoom Webinar. All counsel, members of the public, and media may access the webinar information at https://www.cand.uscourts.gov/hsg. All attorneys and pro se litigants appearing for the case management conference are required to join at least 15 minutes before the hearing to check in with the courtroom deputy and test internet, video, and audio capabilities. The Court further DIRECTS the parties to meet and confer and submit a joint case management statement by October 15, 2024.

IT IS SO ORDERED.

Dated:

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HAYWOOD S. GILLIAM, JR.
United States District Judge

United States District Court
Northern District of California